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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100772-1 WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2003/01215	International filing date (day/month/year) 15.07.2003	Priority date (day/month/year) 19.07.2002
International Patent Classification (IPC) or national classification and IPC C07D 333/34, A61K 31/381, A61P 29/00		
Applicant AstraZeneca AB et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 6 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 30.01.2004	Date of completion of this report 08.11.2004
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2003/01215

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs. _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application☒ claims Nos. 1-3, 5-17

because:

☒ the said international application, or the said claims Nos. 15-16
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-3, 5-17
are so unclear that no meaningful opinion could be formed (*specify*):

Present claims 1-3 and 5-17 relate to an extremely large number of possible compounds. Support within the meaning of Articles 6 PCT and 5 PCT is to be found, however, for only a very small proportion of the compounds. In the present case, the claims so lack support, and the application so lacks

.../...

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.☐ no international search report has been established for said claims Nos. _____☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.☐ See Supplemental Box for further details.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box III.2

disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the opinion has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts related to the exemplified compound and closely related homologous compounds, i.e. those compounds of formula (I) wherein U=sulphur and T, W and M = carbon.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-14, 17</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-14, 17</u>	NO
Industrial applicability (IA)	Claims	<u>1-14, 17</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The applicant's attention is drawn to the fact that the search during Chapter I was incomplete (see Box III). Thus, this opinion is only based on the search that was made.

The following documents are cited in the search report:

- D1) WO 0162713 A1
- D2) WO 0162704 A1
- D3) EP 373836 A1

D1 and D2 disclose similar phenylheteroalkylamine derivatives, which also are inhibitors of nitric oxide synthase and thereby particularly useful in the treatment of inflammatory diseases and pain.

The claimed compounds according to the present application differ from those of D1 and D2 by the presence of the heterocyclic group containing the substituents M, T, U and W instead of a phenyl group. Therefore, the invention claimed in claims 1-14 and 17 is novel.

An inventive step could not be acknowledged for the present application, since formula (I) according to claim 1 is very broad but support is only to be found in one single exemplified compound. Thus, the applicant has not shown that the technical effect is likely to exist for the whole scope of protection according to formula (I). Consequently claims 1-14 and 17 lack inventive step.

D3 relates to structurally related propanamines, which are serotonin and norepinephrine uptake inhibitors. This document only discloses the general state of the art and is not considered to be of particular relevance.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 7 and 8 are not clear and concise (see PCT Art 6), since the expression "...diseases or conditions in which inhibition of nitric oxide synthase activity is beneficial" is speculative and does not define any specific disease or condition.